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EXAMINER	
CHIN, BRAD Y	

ART UNIT	PAPER NUMBER
1744	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,317	MCVEY ET AL.	
	Examiner	Art Unit	
	Brad Y. Chin	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) *1-17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2002 & 14 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/23/03 & 8/14/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-17 and 19 are objected to because of the following informalities:

In claim 1, line 9; in claim 15, line 6; in claim 20, line 11; in claim 23, line 4; claim 26, line 4; and in claim 30, line 4, Applicant should add the conjunction, "and".

In claim 15, line 9; in claim 19, line 3; and in claim 29, lines 4 and 6, Applicant should amend the word, "area" to the word "region" for consistency.

In claim 19, line 2, Applicant should add the word, "a" preceding "carrier gas flow" and amend the word, "the" to the word "a" preceding "rate".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 8-11, 15, 17, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 8-11, 15, and 28, Applicant recites the limitation "the injection zone" in claim 8, line 4; claim 9, line 6; claim 15, line 4; and claim 28, line 5. Applicant recites the limitation, "the dryer" in claim 9, lines 3 and 5; and claim 11, line 6. There is insufficient antecedent basis for these limitations in the claim. It is believed Applicant is referring to the "mixing zone" and the "dehumidifier", respectively.

Regarding claim 17, Applicant fails to particularly point out the subject matter that is being introduced. It is believed Applicant should amend the claim language as follows: "...wherein the means for introducing the liquid includes a metering pump."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 7, 13-18, and 27-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwards et. al. [U.S. Patent No. 6,077,480].

Regarding claim 1, Edwards teaches a vapor decontamination system for decontaminating a defined region, the system comprising:

at least a first duct along which a carrier gas is passed to the defined region (See Fig. 1, supply lines traveling from inlet of filter 22 through carrier gas generator 20, vaporizer 10, and along supply lines 30 into enclosure 32);

a flash vaporizer for vaporizing a liquid (vaporizer 10), which includes an antimicrobial compound, into vapor (See Specification, col. 2, lines 45-46 – hydrogen peroxide vaporizes on contact with the plate), an outlet of the flash vaporizer being connected to the duct for supplying the vapor into the duct for absorption into the carrier gas passing through the duct at a mixing zone (outlet of the flash vaporizer 10 connected to supply lines 30 where the mixture of vaporized hydrogen peroxide and carrier gas pass into the enclosure 32); and

a means for introducing the liquid from a source to the flash vaporizer (See Specification, col. 2, lines 42-45 – hydrogen peroxide is pumped, preferably by an adjustable

metering pump 12 from a cartridge or reservoir 14, and injected at a measured rate in droplets or mist form onto a heated plate 16 in the vaporizer 10).

Regarding claim 7, Edwards further teaches the system further including a microbe trapping filter between the duct and the defined region (filters 22).

Regarding claim 13, Edwards further teaches the system further including at least one additional flash vaporizer and means for introducing liquid connected with the duct (See Figure – at least one flash vaporizer 10 and adjustable metering pumps 12 for introducing liquid hydrogen peroxide stored in cartridges or reservoirs 14 via conduit to the flash vaporizers 10).

Regarding claim 14, Edwards further teaches the system furthering including at least a second duct (See Figure – system provides for two sets of duct or conduit for transporting carrier gas to enclosure 32); and at least a second flash vaporizer and means for introducing liquid connected with the second duct (See Figure – system provides two flash vaporizers 10 and two adjustable metering pumps 12 for introducing liquid hydrogen peroxide stored in cartridges or reservoirs 14 via conduit to the flash vaporizers 10).

Regarding claim 15, Edwards teaches the system further including: a first plurality of monitors connected with the duct upstream of the mixing zone (See Figure; See Specification, col. 3, line 66 to col. 4, line 2 – processors 56 addressing a pre-programmed look up table 58 with each deviation signal to retrieve a corresponding adjustment for each vaporizer); a second plurality of monitors disposed in the defined region (See Figure; See Specification, col. 3, lines 54-55 – plurality of monitors 52 monitor conditions within the enclosure 32); and a controller connected to the monitors for controlling the means for introducing liquid in accordance with monitored conditions in the duct and in the defined region (See Figure; See Specification, col. 3, lines 57-61 – control system includes comparator 54 for comparing the monitored condition

signals from the monitors with pre-selected ideal hydrogen peroxide vapor concentration and other conditions as indicated by reference signals).

Regarding claim 16, Edwards further teaches the system further including fans disposed in the defined region for circulating vapor into partially occluded subregions (See Specification, col. 4, lines 17-21 – The process, optionally, also controls...circulation fans in the enclosure 32...An operator's input 60 enables the operator to adjust the reference signal in each region [of the enclosure 32] to cause higher or lower concentrations in selected regions [of the enclosure 32]).

Regarding claim 17, Edwards further teaches the system wherein the means for introducing the [antimicrobial] liquid includes a metering pump (adjustable metering pump 12).

Regarding claim 18, Edwards teaches a method of decontaminating a defined area, the method comprising:

pumping a carrier gas through a duct to the defined region (See Figure; See Specification, col. 2, lines 56-58 – carrier gas generator 20, such as a pump or container of pressurized gas, pumping the carrier gas through the duct to the enclosure 32); and

injecting an antimicrobial vapor into the duct at a mixing zone upstream of the defined region (See Figure; See Specification, col. 1, line 67 to col. 2, line 2 – a plurality of vaporizers inject vaporized hydrogen peroxide into a stream of carrier gas [upstream of enclosure 32]).

Regarding claim 27, Edwards further teaches the method further including directing antimicrobial vapor in the defined region against at least one surface to be decontaminated (See Specification, col. 4, lines 17-21 – The process, optionally, also controls...circulation fans in the enclosure 32...An operator's input 60 enables the operator to adjust the reference signal in each region [of the enclosure 32] to cause higher or lower concentrations in selected regions [of the enclosure 32]).

Regarding claim 28, Edwards further teaches the method further including:

monitoring concentration of the antimicrobial compound in the vapor in the room and carrier gas conditions in the duct upstream of the mixing zone (See Specification, col. 3, line 54 to col. 4, line 12 – plurality of monitors 52 monitor conditions within the enclosure 32. Monitors include temperature sensors, humidity or vapor concentration sensors, air flow or turbulence sensors, pressure sensors, and the like. Processor 56 addresses a pre-programmed look up table 58, which adjusts the hydrogen peroxide metering pump 12 and the carrier gas regulator 18 to bring monitored conditions to the reference values); and

controlling a rate at which the vapor is supplied to the duct in accordance therewith (See Specification, col. 3, lines 51-61 – control system 50 regulates the introduction of hydrogen peroxide to the vaporizers [and eventually to the duct] in accordance with local conditions within the chamber. The control system includes a comparator 54 for comparing the monitored condition signals from the monitors with pre-selected ideal hydrogen peroxide vapor concentration and other conditions as indicated by reference signals).

Regarding claim 29, Edwards further teaches the method further including:

monitoring concentration of the antimicrobial compound in the vapor in the defined region until the concentration reaches a pre-selected level; and holding the vapor in the defined region without further addition of vapor for a period of time (See Specification, col. 3, line 51 to col. 4, line 21 – control system 50 and plurality of monitors 52 for monitoring the concentration of the antimicrobial compound in the vapor in the defined region where the control system 50 with processor 56 regulates adjustment valves, which adjusts the hydrogen peroxide metering pump 12, i.e. holding the vapor in the defined region to a pre-selected level for decontamination of the defined region without further addition of vapor for a period of time, e.g. the time to decontaminate the enclosure).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 8-9, 11-12, 18, 20-22, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Childers et. al. [U.S. Patent No. 5,876,664].

Regarding claim 1, Childers teaches a vapor decontamination system for decontaminating a defined region, the system comprising:

at least a first duct along which a carrier gas is passed to the defined region (conduit circuit 16 fluidly connected to inlet port 12 and outlet port 14 of sterilizing chamber 10)

a flash vaporizer for vaporizing a liquid (vaporizer unit 18), which includes an antimicrobial compound, into vapor (See Specification, col. 9, line 24-26 – preferred embodiments of the invention provide for an aqueous 35% hydrogen peroxide solution to be flash vaporized), an outlet of the flash vaporizer being connected to the duct for supplying the vapor into the duct for absorption into the carrier gas passing through the duct at a mixing zone (See Specification, col. 7, line 1-5 – the vaporizer unit 18 delivers a vaporized liquid sterilant into carrier gas flow. The vaporizer's 18 outlet is fluidly connected to the conduit circuit 16 where vaporized liquid sterilant is supplied into the duct for absorption into the carrier gas passing through conduit circuit 16); and

a means for introducing the liquid from a source to the flash vaporizer (See Specification, col. 7, lines 5-8 – liquid sterilant is preferably atomized in an atomizer 56 fluidly connected to the vaporizer 18 and delivered to the vaporizer in the form of a fine mist to increase the likelihood of complete vaporization).

Regarding claim 8, Childers teaches the system further including a heater (heater 58) and a dehumidifier (adjustable drying unit 24) connected with the duct upstream from the mixing zone (See Fig. 6 – heater 58 and adjustable drying unit 24 are fluidly connected to the conduit circuit upstream from the mixing zone).

Regarding claim 9, Childers teaches the system as defined in claims 1 and 8. Childers further teaches the duct includes: an inlet upstream of the heater and the dryer connected with the defined region such that the carrier gas is circulated from the duct inlet, through the heater and dryer, through the mixing zone, and through a duct outlet into the defined region (See Fig. 6 – conduit duct 16 includes an inlet upstream from heater 58 and adjustable drying unit 24 connected to chamber 10 at inlet port 12 and outlet port 14 such that the carrier gas is circulated from the duct inlet, through the heater 58 and the dryer 24, through the mixing or injection zone at the outlet of the flash vaporizer 18, and into the inlet port 12 of chamber 10).

Regarding claim 11, Childers teaches the system as defined in claims 1, 8, and 9. Childers further teaches the antimicrobial compound includes hydrogen peroxide (See Specification, col. 9, line 24-26 – preferred embodiments of the invention provide for an aqueous 35% hydrogen peroxide solution to be flash vaporized) and further includes a hydrogen peroxide destroyer for decomposing hydrogen peroxide vapor into water vapor and oxygen (catalytic converter 20 for decomposing hydrogen peroxide to water and oxygen), the destroyer being disposed upstream from the dryer (See Fig. 6 catalytic converter 20 is upstream from adjustable drying unit 24).

Regarding claim 12, Childers further teaches the system including: a source of carrier gas connected with the flash vaporizer (See Figure – circuit conduit 16 carrying carrier gas connected to flash vaporizer 18) for creating a positive pressure differential from the flash vaporizer to the mixing zone (See Specification, col. 8, lines 42-48 – first blower 22a and

second blower 22b positioned upstream from the flash vaporizer and the mixing zone can be adjusted based on feedback from flow sensors 38 and 40 to provide a slightly positive pressure [differential] along the circuit conduit, e.g. from the flash vaporizer to the mixing zone).

Regarding claim 18, Childers teaches a method of decontaminating a defined area, the method comprising:

pumping a carrier gas through a duct to the defined region (blowing unit 22a and 22b serve to push or force the carrier gas around the closed-loop flow path); and

injecting an antimicrobial vapor into the duct at a mixing zone upstream of the defined region (See Specification, col. 7, line 1-5 – the vaporizer unit 18 delivers a vaporized liquid sterilant into carrier gas flow. The vaporizer's 18 outlet is fluidly connected to the conduit circuit 16 where vaporized liquid sterilant is supplied into the duct for absorption into the carrier gas passing through conduit circuit 16 upstream from the inlet port 12 of the defined region – See Figure).

Regarding claim 20, Childers further teaches the method wherein the antimicrobial vapor includes hydrogen peroxide (See Specification, col. 5, lines 39-41 – The sterilant vapor preferably comprises hydrogen peroxide generated from 30-35% by weight of aqueous hydrogen peroxide solution) and further including:

heating a block which has an internal passage to a temperature sufficient to vaporize the hydrogen peroxide but which temperature is lower than a temperature which disassociates hydrogen peroxide; passing hydrogen peroxide into the passage through the block to vaporize the hydrogen peroxide (See Figs. 7 and 8 – series of spaced vaporizer heaters, providing a heat gradient from top to bottom of vaporizer 18 when heat-sensitive vapor, such as hydrogen peroxide vapor, is the sterilant; See Specification, col. 7, lines 15-20 – as the liquid/vapor mixture descends through the tortuous [internal] path, heaters of lower wattage provide less

heat at the middle and the bottom of the vaporizer, so as not to degrade the already-formed vapor, and to vaporize any remaining liquid);

passing the hydrogen peroxide vapor from the passage into the mixing zone; and mixing the hydrogen peroxide vapor into the carrier gas flow (See Fig. 8; See Specification, col. 3, line 1-4 – a [flash] vaporizer comprising an internal tortuous path, having an entrance and an exit, is provided for vaporizing a liquid decontaminant delivered into a [mixing zone] with the flow of carrier gas. The mixing zone is located upstream from the inlet port 12 of the enclosure 10 at the point where the vaporized hydrogen peroxide is injected or introduced to the flow of carrier gas through conduit circuit 16).

Regarding claim 21, Childers further teaches the method including: blowing carrier gas through the passage with the hydrogen peroxide to create a positive pressure differential between the passage and the duct. (See Figure – circuit conduit 16 carrying carrier gas connected to flash vaporizer 18) for creating a positive pressure differential from the flash vaporizer to the mixing zone; See Specification, col. 8, lines 42-48 – first blower 22a and second blower 22b positioned upstream from the flash vaporizer and the mixing zone can be adjusted based on feedback from flow sensors 38 and 40 to provide a slightly positive pressure [differential] along the circuit conduit, e.g. from the flash vaporizer to the mixing zone).

Regarding claim 22, Childers teaches the method as defined in claims 18 and 20. Childers further teaches the method further including heating (heater 58) and drying (adjustable drying unit 24) the carrier gas in the duct upstream of the mixing zone (See Fig. 6 – heater 58 and adjustable drying unit 24 are fluidly connected to the conduit circuit upstream from the mixing zone).

Regarding claim 30, Childers further teaches the method including:

heating a block above a vaporization temperature of a peroxy compound (See Figs. 7 and 8 – block structure of vaporizer 18 housing heaters 60, 61, and 62, providing a heat gradient from top to bottom of vaporizer 18 when heat-sensitive vapor, such as hydrogen peroxide vapor, is the sterilant; See Specification, col. 7, lines 15-20 – as the liquid/vapor mixture descends through the tortuous [internal] path, heaters of lower wattage provide less heat at the middle and the bottom of the vaporizer, so as not to degrade the already-formed vapor, and to vaporize any remaining liquid); and

metering the peroxy compound in liquid form into an internal bore in the block to vaporize the peroxy compound (See Figure 8; See Specification, col. 3, lines 14-19 – metering the liquid hydrogen peroxide into the internal bore, e.g. tortuous path, of the block structure to vaporize the hydrogen peroxide).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Childers. Childers teaches the method as defined in claim 18 above. Childers further teaches the method wherein the carrier gas flow through the duct is at a rate of at least 20 cubic meters per minute (See Specification, col. 2, lines 60-63 – flow rates ranging from only one to two SCFM to flow rates of thousands of SCFM). Childers fails to teach that the defined region is an enclosure of at least 10,000 cubic meters.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an enclosure of at least 10,000 cubic meters because Applicant has not disclosed that an enclosure of at least 10,000 cubic meters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with enclosures of other sizes because of the ability to regulate the flow rate of the incoming and circulating carrier gas and the volume of the liquid hydrogen peroxide. Accordingly, it would have been obvious to modify Childers to obtain the invention with an enclosure of at least 10,000 cubic meters as defined in claim 19.

6. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers in view of Naperkowski et. al. [U.S. Patent No. 5,949,958].

Childers teaches the system as defined in claim 1 above. Childers further teaches the system, wherein the antimicrobial compound includes hydrogen peroxide (See Specification, col. 5, lines 39-41 – The sterilant vapor preferably comprises hydrogen peroxide generated from 30-35% by weight of aqueous hydrogen peroxide solution), and the flash vaporizer includes:

a block (See Fig. 8; block structure of vaporizer 18 housing heaters 60, 61, and 62);

at least one heater for heating and maintaining the vaporizer at or above a vaporization temperature of hydrogen peroxide and below a hydrogen peroxide dissociation temperature (See Figs. 7 and 8 – series of spaced vaporizer heaters, providing a heat gradient from top to bottom of vaporizer 18 when heat-sensitive vapor, such as hydrogen peroxide vapor, is the sterilant; See Specification, col. 7, lines 15-20 – as the liquid/vapor mixture descends through the tortuous path, heaters of lower wattage provide less heat at the middle and the bottom of the vaporizer, so as not to degrade the already-formed vapor, and to vaporize any remaining liquid); and

a passage extending through the heater block from an inlet to the outlet of the flash vaporizer (See Fig. 8; See Specification, col. 3, line 1-4 – a [flash] vaporizer comprising an internal tortuous path, having an entrance and an exit, is provided for vaporizing a liquid decontaminant delivered into a flow of carrier gas through the tortuous path).

Childers fails to teach the system wherein (1) the block is metal; (2) the passage expands in cross section between the inlet and the outlet; (3) the passage turns at least 180° between the inlet and the outlet; (4) the passage includes at least two turns of approximately 90° and a wall therebetween, such that the liquid in the passage strikes the wall, thereby increasing a vaporization rate of the liquid antimicrobial compound; and (5) a plurality of

interconnected bores extending back and forth through the block between the inlet and the outlet.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the block of Childers out of metal, since it has been held within the general skill of an individual in the art to select metal on the basis of its suitability to transfer heat and withstand substantial system pressures as a matter of obvious engineering choice. *In re Leshin*, 125 U.S.P.Q. 416.

Naperkowski teaches each of the missing aspects of Childers identified above.

Naperkowski teaches a system for flash vaporization of a liquid to a gas comprising a metal block (11). Naperkowski teaches that the metal block is constructed out of metal, more particularly carbon steel or any other heat-transferring metal (See Specification, col. 3, lines 17-19). Naperkowski further teaches the system wherein the passage extending through the metal block expands in cross section between the inlet and the outlet (See Fig. 5; spiral rod 45 inserted in first bore 12 creates a tortuous passage which expands in cross section, i.e. between the inlet and the outlet, the tortuous passage expands as the liquid/vapor antimicrobial compound moves along the passage from the center of the spiral rod to the outer portions of the spiral rod). Naperkowski further teaches that the passage turns at least 180° between the inlet and the outlet (See Fig. 5; the passage turns at least 180° around the spiral rod as the liquid/vapor mixture travels between the inlet and the outlet). Naperkowski further teaches that the passage includes at least two turns of approximately 90° and a wall therebetween, such that the liquid in the passage strikes the wall, thereby increasing a vaporization rate of the liquid antimicrobial compound (See Fig. 5; the passage includes at least two turns of approximately 90° and a wall therebetween, such that the liquid in the passage frequently makes contact with the heated surfaces of the flash vaporizer, providing, with the increased residence time, a more

efficient and rapid generation of drier, more desirable vaporized antimicrobial compound – See Specification, col. 5, lines 18-24). Naperkowski also teaches that the passage includes a plurality of interconnected bores extending back and forth through the block between the inlet and the outlet (See Figs. 7 and 8; See Specification, col. 5, lines 25-28 – plurality of interconnected bores extending back and forth through the block between the inlet and the outlet).

Childers' continuous-operation, closed loop decontamination system requires the use of a flash vaporizer comprising at least one heater for controlling the heat within the vaporizer block and a tortuous passage for the liquid/vapor mixture to travel through from the inlet to the outlet of the flash vaporizer. Naperkowski teaches a flash steam generator [vaporizer], which can be used as an integral component of a sterilizer, which also includes at least one heater and a tortuous passage for liquid/vapor mixture to travel through from the inlet to the outlet of the flash vaporizer as liquid sterilant is vaporized. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the flash vaporization generator 10 of Naperkowski for the flash vaporizer 18 of Childers because Naperkowski's system provides the functionality of vaporizing the liquid/vapor sterilant mixture as required by the system in Childers.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Childers in view of Edwards.

Childers teaches the system as defined in claims 1 and 9 above. Childers' system further provides for a source of external carrier gas metered into the circuit conduit 16 by toggling open valve 74 (See Specification, col. 8, lines 60-62; See Fig. 7). Childers fails to teach microbe trapping filters disposed adjacent the duct inlet and the duct outlet.

Edwards teaches a microbe-trapping filter disposed adjacent to the duct inlet for filtering the incoming carrier gas, but fails to further teach a microbe-trapping filter disposed adjacent to the duct outlet.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a microbe-trapping filter disposed adjacent to the duct inlet of Childers, as in Edwards, for filtering the incoming carrier gas because the microbe-trapping filter would serve to remove impurities that may be present in the incoming carrier gas before passing the carrier gas into the circuit conduit 16. Similarly, it would have been obvious to one of ordinary skill in the art to provide additional microbe-trapping filters in the system of Childers, i.e. at the outlet of the duct prior to injecting the vaporized hydrogen peroxide/carrier gas mixture into the sterilization chamber 10 because it would have been a desired condition of the system to provide the purest sterilant composition as possible in decontaminating the sterilization chamber. Providing additional microbe-trapping filters throughout Childers' system would increase the purity of the constituents in the system (Duplicating part for a multiple effect – *In re Harza*, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960)).

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers in view of Edwards.

Childers teaches the method as defined in claim 18 above. Childers' method further includes pulling carrier gas with antimicrobial vapor from the enclosed area (See Figure – blowing units 22a and 22b pushes or forces the carrier gas around the closed-loop flow path, i.e. pulls the carrier gas with antimicrobial compound out outlet port 14 of chamber 10 through conduit circuit 16), but fails to teach that the carrier gas with antimicrobial vapor is pulled through a microbe-trapping filter. Childers' method further includes drying and heating the

carrier gas and passing the dried, heated carrier gas to the duct upstream of the mixing zone (See Figure – adjustable drying unit 24 downstream from outlet port 14 and converter 20, and heaters 58a and 58b for heating the carrier gas; passing the dried, heated carrier gas through the duct into vaporizer 18, upstream of the mixing zone, e.g. outlet of vaporizer 18 after new liquid hydrogen peroxide has been vaporized). Childers fails to teach that the carrier gas with antimicrobial vapor from the enclosed area is pulled through a microbe-trapping filter.

Edwards teaches a microbe-trapping filter disposed adjacent to the duct inlet for filtering the incoming carrier gas.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a microbe-trapping filter, as in Edwards, for filtering the pulled carrier gas with antimicrobial vapor from the enclosed area because the microbe-trapping filter would serve to remove impurities that may be present in the exiting carrier gas/vaporized sterilant mixture before passing the carrier gas back into circuit conduit 16. Similarly, it would have been obvious to one of ordinary skill in the art to provide additional microbe-trapping filters in the system of Childers, i.e. a microbe-trapping filter near the outlet port 14 of chamber 10 for filtering the pulled carrier gas with antimicrobial vapor from the enclosed area because it would have been a desired condition of the system to purify the carrier gas as much as possible before introducing and mixing new, pure carrier gas from an external source into the conduit circuit 16. Providing additional microbe-trapping filters throughout Childers' system would increase the purity of the constituents in the system (Duplicating part for a multiple effect – *In re Harza*, 274 F.2d 669, 671, 124 USPQ 378, 380 (CCPA 1960)).

9. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers in view of Raniwala [U.S. Patent No. 6,645,429].

Childers teaches the method as defined in claim 18 above. Childers fails to teach that the defined region is a large room and the duct includes existing HVAC work. Childers further fails to teach the method further including supplying carrier gas through a plurality of ducts into the room; and injecting hydrogen peroxide vapor into the carrier gas in each of the ducts.

Raniwala teaches a sterilization system and method wherein the defined region is a large room (See Specification, col. 3, line 51-54 – clean room, or series of clean rooms or enclosed rooms) and the duct includes existing HVAC duct work (HVAC system 29), where carrier gas is supplied through a plurality of ducts into the room and/or sterilizing agent is injected into the room through each of the ducts (See Specification, col. 4, lines 13-17 – HVAC system 29 can form part of the sterilizing system for room 10 for introducing sterilizing agent into atmosphere 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method of Childers for decontaminating a defined region into the system of Raniwala because Raniwala's HVAC existing duct work provides for multiple feeds of a sterilizing agent, such as the mixtures of vaporized hydrogen peroxide and carrier gas of Childers, into the contaminated room, allowing the user to regulate the concentration and amount of vaporized hydrogen peroxide dispersed into the room.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Childers in view of Rickloff et. al. [U.S. Patent No. 5,445,792].

Childers teaches the method as defined in claims 18 and 30 above. Childers fails to teach the method further including entraining the liquid peroxy compound into a controlled air flow upstream from the block.

Rickloff teaches the method of sterilization with hydrogen peroxide where the liquid peroxy compound is entrained into a controlled air flow upstream from the vaporizer (See Figure 1; liquid hydrogen peroxide from source 10 is entrained into a controlled air flow of carrier gas, air, from ROOM AIR, by regulating three-way valve 16 (flow paths A-C and B-C), upstream from vaporizer 14 [and the block of vaporizer 14]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method of Rickloff for entraining the liquid peroxy compound into a controlled air flow upstream of the vaporizer into the block of the vaporizer of Childers' system because controlling the flow rate of the air flow containing liquid peroxy compound into the vaporizer would provide the user with the ability to regulate the vaporization rate of the peroxy compound in response to the parameters monitored by the processing unit and the respective temperature 44, relative humidity 46, and vapor concentration 48 sensors within chamber 10.

11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Childers and Rickloff as applied to claims 18, 30, and 31 above, and further in view of Naperkowski.

Childers and Rickloff teach the methods as defined in claims 18, 30 and 31 above. Childers and Rickloff fail to teach the method wherein the internal bore turns and further including propelling peroxy compound droplets into bore surfaces at turns in the internal bore.

Naperkowski teaches a system for flash vaporization of a liquid to a gas comprising a metal block vaporization system having an internal bore with a spiral rod (spiral rod 45 inserted in first bore 12) and further teaches a method for propelling droplets into bore surfaces at turns in the internal bore (See Specification, col. 5, lines 15-20 – spiral rod creates a tortuous path for the water and steam as it passes upwardly through the bore. The spiral rod creates an environment in which the water and steam frequently contact heated surfaces within the

vaporization device, i.e. as it travels from the inlet to the outlet of the vaporization system, the mixture is propelled against the bore surfaces at turns in the spiral rod in the internal bore. As the mixture contacts the heated surfaces – heated by heating elements 15 – the mixture is vaporized).

Childers's continuous-operation, closed loop decontamination system requires the use of a flash vaporizer comprising at least one heater for controlling the heat within the vaporizer block and a tortuous passage for the liquid/vapor peroxy compound mixture to travel through from the inlet to the outlet of the flash vaporizer. Naperkowski teaches a flash steam generator [vaporizer], which can be used as an integral component of a sterilizer, which also includes at least one heater and a tortuous passage for a mixture, such as a peroxy compound, to travel through from the inlet to the outlet of the flash vaporizer as liquid sterilant is vaporized. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the flash vaporization generator 10, and accordingly an internal bore that turns, providing propelling a mixture into the bore surfaces at turns in the internal bore to facilitate vaporization, of Naperkowski for the flash vaporizer 18 of Childers because Naperkowski's system provides the functionality of vaporizing the liquid/vapor sterilant mixture as required by the system in Childers.

Allowable Subject Matter

12. Claim 33 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: The subject matter of claim 33 could either not be found or was not suggested in the prior art. Claim 33 includes the limitations for the method of decontaminating an enclosure of introducing two carrier gas streams and an aqueous solution of a peroxy compound into a passage, where

a first carrier stream and the aqueous solution of peroxy compound are introduced, mixed, and vaporized therein, and then subsequently mixing the resulting vaporized solution with the second carrier gas downstream of the passage. The closest prior art of Rickloff teaches (1) the introduction, mixing, and vaporization of the first carrier stream with the aqueous hydrogen peroxide and (2) the existence of a second carrier gas, but fails to teach the mixing of the second carrier gas with the resulting vaporized solution downstream of the passage.

None of the references teach the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter; thus, claim 33 is free of the prior art and is allowable.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
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